### UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al., Case No. 17-op-45004 (N.D. Ohio)

MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

REPLY IN SUPPORT OF PHARMACY DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' CIVIL CONSPIRACY CLAIM

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#### INTRODUCTION

Plaintiffs' consolidated conspiracy brief is long on insinuation and rhetoric but markedly short on facts from which a jury could find that any Pharmacy Defendant entered into the sweeping industry-wide conspiracy that Plaintiffs allege. Indeed, the bulk of Plaintiffs' omnibus brief concerns RICO claims and an alleged marketing conspiracy that Plaintiffs concede have nothing at all to do with Pharmacy Defendants. *See* Pls. Resp. Br. 7-31, 74-101 (Dkt. 2182) ("Resp.").

A civil conspiracy claim under Ohio law requires proof that defendants entered a malicious combination, or, put differently, that defendants shared "a common understanding or design, even if tacit, to commit an unlawful act." *Woodward Constr., Inc. v. For 1031 Summit Woods, L.L.C.*, 2015-Ohio-975, ¶¶ 22-24 (Ohio Ct. App. 2015) (quotation omitted). Plaintiffs cite no evidence showing that Pharmacy Defendants did anything of the sort. What little evidence Plaintiffs cite shows only that Pharmacy Defendants were members of an industry trade association that lobbied about certain regulations and submitted amicus briefs on certain legal issues; that a different trade association of which Pharmacy Defendants were *not* members worked with the Drug Enforcement Administration ("DEA") to develop voluntary industry guidelines; and that some Pharmacy Defendants relied on some Distributor Defendants to supply their pharmacies. Much of this evidence involves conduct protected by the First Amendment. None of it suggests a malicious combination. And the only "facts" asserted against Pharmacy Defendants—other than their membership in a trade association—concern business operations for which they are not sued (their

<sup>&</sup>lt;sup>1</sup> "Pharmacy Defendants" are CVS Rx Services, Inc. and CVS Indiana, L.L.C. ("CVS Distributors"); Discount Drug Mart ("DDM"); HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"); Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"); Walgreen Co. and Walgreen Eastern Co. ("Walgreens"); and Walmart Inc. ("Walmart"). Pharmacy Defendants adopt and incorporate by reference the relevant portions of Defendants' Civil Conspiracy, RICO, and OCPA Reply Brief, filed concurrently.

pharmacy businesses) and that the Court determined were excluded from the case. *See* Court Order 2 (Dkt. 1203) ("[T]he Retail Pharmacies may only be held liable as distributors.").

Pharmacy Defendants' opening memorandum explained that Plaintiffs must present actual evidence of a malicious combination before their claim can go to a jury, as "speculation and conjecture . . . [are] insufficient as a matter of law." Pharmacy Dfts. MSJ Br. 17 (Dkt. 1875-3) ("MSJ") (quoting *Woodward Constr.*, 2015-Ohio-975, ¶ 2). Conduct that is equally "consistent with permissible competition as with illegal conspiracy" is not enough. *Id.* (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986)). After thousands of pages of discovery and hundreds of depositions, Plaintiffs do not come close to meeting this burden.

#### **ARGUMENT**

I. Plaintiffs Do Not Allege That Pharmacy Defendants Were Part Of Any RICO Enterprise Or Conspiracy To Market Prescription Opioids.

Plaintiffs' consolidated conspiracy brief melds together the various defendants in an apparent effort to create the gestalt impression of a conspiracy. The bulk of the brief, however, has nothing to do with Pharmacy Defendants. Plaintiffs do not even *allege* that Pharmacy Defendants were part of a RICO enterprise. Resp. 3 (listing the members of the alleged RICO enterprise). And Plaintiffs nowhere suggest that Pharmacy Defendants engaged in a conspiracy to market opioids, instead conceding that their claims against Pharmacy Defendants "are Not Based on Opioid Marketing." *Id.* at 114. The vast majority of alleged wrongdoing attributed to the so-called conspiracy has nothing to do with Pharmacy Defendants.

II. "Protecting The Supply Chain" Is Neither A Viable Civil Conspiracy Theory Nor Supported By Any Record Evidence.

Putting the RICO enterprise and marketing conspiracy allegations to the side, what Plaintiffs *do* levy against Pharmacy Defendants is a vague and novel allegation that Pharmacy Defendants were part of a "conspiracy to protect the supply chain." Resp. 108. Under this theory,

Pharmacy Defendants can supposedly be lumped into an industry-wide conspiracy because they shared an objective to ensure that medications were available to fill prescriptions. Plaintiffs' theory fails both for lack of evidence and as a matter of law.

A. Plaintiffs Provide No Evidence Of A Conspiracy to Violate the SOM Regulation, Which Would Not Constitute An "Unlawful Purpose" In Any Event.

The fundamental problem with Plaintiffs' theory is that malicious combination requires a shared purpose to violate the law, and a purpose to distribute opioid medications to fill legitimate prescriptions is in no sense unlawful. To the contrary, Pharmacy Defendants were licensed to do precisely that by federal law, which recognizes that opioids "have a useful and legitimate medical purpose," 21 U.S.C. § 801(1).<sup>2</sup> Plaintiffs readily concede that Pharmacy Defendants did nothing to increase demand for opioid medications through marketing. Resp. 114. Plaintiffs' conspiracy theory thus necessarily amounts to a claim that Pharmacy Defendants "conspired" to distribute lawful medications, approved by the Food and Drug Administration, to fill prescriptions written by medical professionals, in amounts that fell comfortably within DEA expected ratios for the percentages of controlled substances dispensed by legitimate pharmacies, see, e.g., Walmart MSJ 5-6 (Dkt. 1864-3). That is legitimate business activity, not the sort of malicious aim necessary to support a claim of conspiracy.<sup>3</sup>

Apparently in an attempt to cobble together the "unlawful purpose" element of their claim, Plaintiffs suggest that Pharmacy Defendants conspired to violate the SOM regulation. *See* Resp.

<sup>&</sup>lt;sup>2</sup> Of course, DEA's core missions include ensuring an adequate and uninterrupted supply of medications to meet the country's legitimate medical needs and preventing diversion of controlled substances. *See, e.g.,* 21 U.S.C. §§ 824 to 827; 21 C.F.R. §§ 1301 *et seq.* 

<sup>&</sup>lt;sup>3</sup> The opening memorandum cites numerous cases holding that distributors do not conspire with pharmaceutical manufacturers merely by distributing those manufacturers' products. *See* MSJ 10. Plaintiffs say those cases are "factually distinct," Resp. 108, but, apart from alleged SOM violations addressed *infra*, never bother to say what material facts they believe distinguish those cases. In fact, no distinctions exist.

112. But even if they could establish the existence of SOM shortcomings (and they cannot),<sup>4</sup> Plaintiffs present no evidence that such shortcomings were the *product* of a malicious combination. Plaintiffs attempt to distinguish *Parker v. Eli Lilly*, No. CV-274501, 1996 WL 1586780 (Ohio C.P. Jun. 21, 1996), on the ground that defendants all "knew the CSA requirements," but the fact that defendants were aware of their obligation to prevent diversion does not remotely suggest they worked together to violate it. To the contrary, each distributor is required to separately monitor its own supply chain, and distributors can meet (or not meet) that obligation without any need to "conspire." As explained below, none of the evidence that Plaintiffs cite in their brief suggests that alleged SOM shortcomings—assuming there were any—were anything more than parallel conduct.<sup>5</sup>

Moreover, allegations of SOM shortcomings cannot supply the necessary unlawful purpose for a conspiracy claim, because Ohio law is clear that the "underlying unlawful act must be a tort." *Avery v. Rossford, Ohio Transp. Improvement Dist.*, 145 Ohio App. 3d 155, 165 (Ohio Ct. App. 2001). As explained elsewhere, Plaintiffs cannot fit their criticisms of individual defendants' SOM compliance within the elements of their common law claims, and in fact federal law preempts their attempt to do so. *See, e.g.*, Defts' Resp. to CSA Compliance Br. 11-14 (Dkt. 2149) ("CSA Compliance Resp."). There is no such thing as a state-law conspiracy to violate DEA regulations.

<sup>&</sup>lt;sup>4</sup> Pharmacy Defendants dispute that they violated the SOM regulation. *See* Defts' Resp. to CSA Compliance Br. 56-102 (Dkt. 2149). But the Court need not resolve that issue to grant summary judgment on the conspiracy claim. Regardless of whether Pharmacy Defendants violated the SOM regulation, there is no evidence that they conspired with the other defendants to do so.

<sup>&</sup>lt;sup>5</sup> For instance, while Plaintiffs cite DEA settlements with CVS and a DEA settlement with Walgreens, none of the settlements alleged concerted conduct or even concerned common facts. The CVS settlements did not even concern suspicious order monitoring, *see* CSA Compliance Resp. 77, and in any event, all of the settlements are inadmissible under Fed. R. Evid. 408. *See Hobart Corp. v. Dayton Power & Light Co.*, No. 13-cv-115, 2017 WL 5956911, at \*21 (S.D. Ohio Nov. 30, 2017) (holding that Rule 408 barred "the content of prior settlement agreements"); *Mass. Mut. Life Ins. Co. v. DLJ Mortg. Capital, Inc.*, 251 F. Supp. 3d 329, 332 (D. Mass. 2017) (holding that Rule 408 barred defendant's prior settlement with DOJ and factual assertions acknowledged in it).

# B. Participation In Legitimate Trade Associations Is Not Evidence That Pharmacy Defendants Were Part Of A Conspiracy.

Plaintiffs suggest that Pharmacy Defendants can be held liable because they were members of a trade association—NACDS—that supposedly endeavored "to protect the supply chain" by "passing legislation," "coordinating *amicus curiae* briefs," drafting "crisis response documents and talking points," "reporting about DEA" to regulatory watchdogs, and "coordinating ... pending litigation." Resp. 42-43. But the law is clear: Pharmacy Defendants cannot be held liable based on their membership in an association even if it were, as Plaintiffs allege, engaged in such political advocacy. "Not only do these actions not constitute torts, they are protected by the first amendment." *Senart v. Mobay Chem. Corp.*, 597 F. Supp. 502, 506 (D. Minn. 1984); *see also Huron Valley Hosp., Inc. v. City of Pontiac*, 650 F. Supp. 1325, 1341 (E.D. Mich. 1986) ("use of the regulatory process" does not provide a basis for liability). "In short, what [Plaintiffs] attempt[] to characterize as a conspiracy is more accurately and commonly known as free expression and political organizing." *Eaton v. Newport Bd. of Educ.*, 975 F.2d 292, 297 (6th Cir. 1992).

Plaintiffs say they "do not attempt to impose liability upon the Pharmacy or Distributor Defendants for their lobbying activities," Resp. 116, but of course that is exactly what Plaintiffs are trying to do by relying on activities of a pharmacy trade association as their primary proof of a malicious combination. As Pharmacy Defendants explained in their opening brief, the Third Circuit's decision in *In re Asbestos School Litigation*, 46 F.3d 1284 (3d Cir. 1994), shows the First Amendment is not so easily circumvented. There, the Third Circuit held that participation in the association's protected First Amendment activity could not be used to prove a civil conspiracy. *Id.* at 1290 (citing *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 924 (1982)). Only acts "specifically intended to further [non-protected and illicit] conduct" could be used to establish the conspiracy claim, as a contrary rule would unduly chill public debate. *Id.* at 1290, 1294. Plaintiffs

do not even mention *In re Asbestos School Litigation*, much less explain why the same rationale should not bar the claims in this case too.<sup>6</sup>

Plaintiffs may disagree with certain perspectives taken by the trade organizations as they were expressed to the industry and DEA, but that does not make those positions tortious. And even assuming for the sake of argument that they were, being a member of an organization does not mean that one participated in, let alone directed, every one of that organization's efforts. In any event, individual and organizational entities have a "right to present views to the government." *Senart*, 597 F. Supp. at 506; *see also id.* ("[F]irst amendment rights to petition the government include advocating positions before administrative agencies."). Participating in a trade organization or advocating to DEA is not wrongful conduct; Plaintiffs must put forth evidence of some other wrongful conduct that this activity supposedly furthered. They have not done so.

# C. HDA's Efforts To Establish Voluntary Guidelines Are Not Evidence That Pharmacy Defendants Were Part Of A Conspiracy To Violate The Law.

In addition to NACDS's protected First Amendment activity, Plaintiffs also dwell on efforts by HDA, another trade association, to work with DEA to establish voluntary industry guidelines. Resp. 44-46. According to Plaintiffs, HDA's guidelines were a "Ruse to Avoid Regulatory Enforcement," *id.* at 44, as various defendants supposedly had "no intention to implement or comply" with the best practices the group created. *Id.* at 106.

This fabulously counterintuitive argument fails for a host of reasons beyond the fatal fact

<sup>&</sup>lt;sup>6</sup> Plaintiffs' cited cases are not to the contrary, because they simply hold that a defendant's *own* lobbying activity may be introduced as evidence of that defendant's *own* state of mind. *See* Resp. 87 n.478. That is not what Plaintiffs are trying to do here. Instead, Plaintiffs claim that association to engage in First Amendment activity can be used to prove that Defendants associated to engage in non-protected activity as well, which is exactly the type of inference that is barred. *See In re Asbestos School Litigation*, 46 F.3d at 1288-94; *Senart*, 597 F. Supp. at 506 ("Defendants also readily admit that their opposition to the [] proposal was based on their concern that the new proposal would harm their businesses. Nevertheless, selfish motivations do not lessen one's right to present views to the government."). Nor may Pharmacy Defendants somehow be "guilt[y] by association," as there is "no evidence that the association possessed unlawful aims," *Claiborne Hardware Co.*, 458 U.S. at 925.

that Pharmacy Defendants were not even members of HDA.<sup>7</sup> First, HDA's interactions with DEA, a branch of government, are subject to the same First Amendment protections just discussed. Second, a civil conspiracy claim must be based on an intentional tort, *see supra* 4, and working to develop best practices in a regulated area is not a tort. To the contrary, countless industries adopt voluntary guidelines to achieve regulatory compliance; it is absurd to use that as evidence of a conspiracy to commit wrongdoing. Third, to the extent Plaintiffs hinge their claim on the purported deceptive effect those best practices had on DEA, the argument is preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001), which holds that claims of fraud on a federal agency can only be brought by the agency as a matter of federal law. *See* Pharmacy Defts' Preemption MSJ 4-5 (Dkt. 1883-1). Just as the plaintiff in *Buckman* could not pursue a claim for "fraud on the FDA," Plaintiffs cannot save their conspiracy claim by recasting it as one for "fraud on DEA."

Plaintiffs' claim also lacks record support. Most obviously, Pharmacy Defendants were not members of HDA and are not responsible for its conduct. *See* MSJ 5. And while Plaintiffs note that HDA listed NACDS among the guidelines' "external stakeholders," Resp. 45, at most, that simply confirms that NACDS was "external" to the process. Plaintiffs suggest that DEA was somehow under the misguided impression that the guidelines would be mandatory for the entire industry, but the only support that Plaintiffs cite is a reference by HDA to the guidelines as a "voluntary 'consent decree." *Id.* (emphasis added). In fact, DEA has made clear there is no one-size-fits-all solution to SOM, meaning each registrant should develop a SOM program to fit its

<sup>&</sup>lt;sup>7</sup> While a CVS entity not named in these suits became an "affiliate" member of HDA in 2008 (when it acquired a pharmacy benefit manager with such an "affiliate" membership), no CVS entity has ever held a full membership, held an HDA board seat or position, or been part of any HDA committee, task force, or working group. See MSJ 5 n.4. Plaintiffs cite no evidence that any CVS entity played any role in—or even knew about or received a copy of—the HDA guidelines on which Plaintiffs based the purported conspiracy.

unique business. *See, e.g.*, Prevoznik Dep. Tr. 179:22-180:15 (Dkt. 1983-9). There is no evidence in the record that DEA even *wanted* HDA's guidelines to be binding on all industry participants, much less that DEA somehow believed that to be the case.<sup>8</sup>

Finally, this HDA-related conspiracy theory makes no sense, as Plaintiffs cannot even say what this supposed fraud on DEA would have been intended to accomplish. Plaintiffs claim the opioid crisis was fueled by an upsurge in *lawful* prescriptions resulting from Manufacturers' marketing scheme. *See* Resp. 1. That is not something in which Pharmacy Defendants are alleged to have played any role, and, in any event, DEA was aware of (and authorized) the increasing volume of opioids manufactured. *See* CSA Compliance Resp. 2-4.9 Pharmacy Defendants did not conspire to "conceal" information that DEA already knew. Moreover, DEA audited and thus monitored Pharmacy Defendants' *actual* SOM programs. Plaintiffs' suggestion that HDA lulled the DEA into rubber-stamping their SOM programs is a pure invention, unmoored from record evidence, that would not make out a conspiracy even if it were true.

# D. Particular Pharmacies' Customer Relationships With Particular Distributor Defendants Are Not Evidence Of An Industry-Wide Conspiracy.

Finally, Plaintiffs focus on the fact that some Pharmacy Defendants, in addition to self-distributing, also ordered products for their pharmacies through Distributor Defendants. *See* Resp. 59-73. Plaintiffs point to these customer relationships in an attempt to show that particular

<sup>&</sup>lt;sup>8</sup> Plaintiffs in fact cite evidence that these guidelines were not intended to be applied to self-distributing pharmacies, Resp. 46, which is what Pharmacy Defendants were when they were in the business of distribution. Plaintiffs view that as somehow a problem, but it is entirely appropriate for self-distributors to take a different approach to SOM, as self-distributors have different relationships with their customers. *See, e.g.*, Tongring Rpt. 2 (Dkt. 1936-32); Wright Dep. Tr. Vol. I 128:21-129:1 (Dkt. 1985-24); Mapes Dep. Tr. 238:19-239:16 (Dkt. 2173-40).

<sup>&</sup>lt;sup>9</sup> For this reason, Plaintiffs' reliance on *Direct Sales Co. v. United States*, 319 U.S. 703 (1943), is inapposite. That case involved a distributor that operated a "direct mail" business and supplied a doctor who "dispensed illegally vast quantities of morphine sulphate purchased by mail." *Id.* at 704. The defendant provided these controlled substances "in such quantities, so frequently and over so long a period it must have known [the doctor] could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally." *Id.* at 705. By contrast, Plaintiffs' theory is that the volume of opioids distributed here was in line with prevailing medical thought—but that medical thought was unduly influenced by manufacturers without participation from Pharmacy Defendants.

Pharmacy Defendants supposedly coordinated with particular Distributor Defendants to violate SOM regulation. These arguments fail for three reasons.

First, these allegations concern alleged conduct for which Plaintiffs have not sued Pharmacy Defendants. As the Court has explained, Plaintiffs sue Pharmacy Defendants only in their capacity as distributors. See Court Order 2 ("[T]he Retail Pharmacies may only be held liable as distributors."). Yet in their opposition, Plaintiffs point to evidence of purported conspiracy based on particular Pharmacy Defendants' conduct not as distributors but instead as pharmacies in placing orders with other distributors. Such conduct falls outside the four corners of the complaints, which allege only that manufacturers and distributors conspired with each other—not that distributors conspired with their pharmacy customers. 10

Second, these allegations pertain to customer relationships between particular pharmacies and particular supplier distributors, and therefore do not prove the existence of the kind of industry-wide conspiracy that Plaintiffs allege. See, e.g., Spectators' Commc'n Network Inc. v. Colonial Country Club, 253 F.3d 215, 224 (5th Cir. 2001) (citing cases for the proposition that the existence of separate vertical relationships within an industry does not establish the existence of a horizontal conspiracy). Even if Plaintiffs could show that a pharmacy coordinated with its own supplier to violate the law, it would not follow that the pharmacy conspired with a whole industry of other distributors and manufacturers as Plaintiffs allege.

<sup>&</sup>lt;sup>10</sup> Buried amidst allegations relating to orders by CVS pharmacies to an outside distributor (Cardinal), which are not the subject of the actual claims against CVS, Plaintiffs allege that Cardinal did not monitor its separate shipments to CVS distribution centers. Even assuming this to be true, Plaintiffs cite no evidence indicating that it was the subject of agreement with CVS (or even that CVS knew about it). Nor do they dispute that CVS's own systems would have monitored the subsequent shipment of those drugs from CVS distribution centers to CVS pharmacies. *See* CSA Compliance Resp. 77-84. While Plaintiffs separately criticize CVS for a document indicating that CVS itself would not report to DEA a suspicious order a pharmacy placed with Cardinal (if it somehow ever identified one), that is exactly how the regulation operates. *Id.* at 84 n.243. And in any event, Plaintiffs cite no evidence that this ever occurred. This is hardly is proof of conspiracy.

Third, although Plaintiffs' factual allegations are insufficient to establish a conspiracy as a matter of law, it is worth underscoring that Plaintiffs do not even offer evidence of discrete wrongdoing. To take just one example, the "facts" that Plaintiffs argue establish claims against Walmart and HBC Giant Eagle are notable for their brevity; they are set forth in two sentences combined out of a 118-page brief. Resp. 71. What few facts Plaintiffs put forward against any Pharmacy Defendant seem designed to invite the Court to infer that certain communications between a Distributor Defendant and a Pharmacy Defendant were to avoid reporting transactions to DEA. There is no factual basis in the record to support such an interference. There is no evidence, for instance, that the intent of any distributor in notifying a Pharmacy Defendant that it was approaching a threshold was unlawful in any respect. Indeed, the effect of the threshold notifications was just as likely to reduce the amount of opioid medications shipped. Nor is there any evidence that any Pharmacy Defendant shared in any allegedly bad intent by distributors, or that such practice actually resulted in information being concealed from DEA or anyone else. More to the point, Plaintiffs have not presented evidence of any wrongdoing. There are obvious, legitimate medical reasons for pharmacies and their suppliers to work together to avoid "supply chain disruption." *Id.* at 61. Otherwise, patients will not have access to medications they need.

Plaintiffs attempt to manufacture "factual issues" to stave off summary judgment. But conspiracy claims cannot survive summary judgment based on insinuation and innuendo, unbacked by evidence. *See Magnum Steel & Trading, L.L.C. v. Roderick Linton Belfance, L.L.P.*, 41 N.E.3d 204, 208 (Ohio Ct. App. 2015). The Court should grant Pharmacy Defendants' motion.

#### CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of Pharmacy Defendants on Plaintiffs' civil conspiracy claim.

Dated: August 16, 2019 Respectfully submitted,

#### /s/ Tara A. Fumerton

Tina M. Tabacchi Tara A. Fumerton JONES DAY 77 West Wacker Chicago, IL 60601 Phone: (312) 269-4335

Fax: (312) 782-8585

E-mail: tfumerton@jonesday.com

Attorneys for Walmart Inc.

#### /s/ Eric R. Delinsky (consent)

Eric R. Delinsky Alexandra W. Miller ZUCKERMAN SPAEDER LLP 1800 M Street, NW **Suite 1000** Washington, DC 20036

Phone: (202) 778-1800 Fax: (202) 822-8106

E-mail: edelinsky@zuckerman.com E-mail: smiller@zuckerman.com

Attorneys for CVS Rx Services, Inc. and CVS Indiana, L.L.C.

#### /s/ Robert M. Barnes (consent)

Robert M. Barnes Scott D. Livingston Joshua A. Kobrin MARCUS & SHAPIRA, LLP 35th Floor, One Oxford Centre 301 Grant Street

Pittsburgh, PA 15219 Phone: (412) 471-3490 Fax: (412) 391-8758

E-mail: rbarnes@marcus-shapira.com E-mail: livingston@marcus-shapira.com E-mail: kobrin@marcus-shapira.com

Attorneys for HBC Service Company

#### /s/ Kaspar Stoffelmayr (consent)

Kaspar Stoffelmayr BARTLIT BECK LLP 54 West Hubbard Street Chicago, IL 60654

Phone: (312) 494-4400 Fax: (312) 494-4440

E-mail: <u>kaspar.stoffelmayr@bartlit-beck.com</u>

Attorney for Walgreen Co. and Walgreen Eastern Co.

### /s/ Kelly A. Moore (consent)

Kelly A. Moore
MORGAN, LEWIS & BOCKIUS LLP
101 Park Avenue
New York, NY 10178
Phone: (212) 300 6612

Phone: (212) 309-6612 Fax: (212) 309-6001

E-mail: kelly.moore@morganlewis.com

Elisa P. McEnroe MORGAN, LEWIS & BOCKIUS LLP

1701 Market Street Philadelphia, PA 19103 Phone: (215) 963-5917 Fax: (215) 963-5001

E-mail: elisa.mcenroe@morganlewis.com

Attorneys for Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center

#### /s/ Timothy D. Johnson (consent)

Timothy D. Johnson
Gregory E. O'Brien
CAVITCH FAMILO & DURKIN, CO. LPA
Twentieth Floor
1300 East Ninth Street
Cleveland, OH 44114

Phone: (216) 621-7860 Fax: (216) 621-3415

Email: tjohnson@cavitch.com Email: gobrien@cavitch.com

Counsel for Discount Drug Mart, Inc.

## **CERTIFICATE OF COMPLIANCE WITH LOCAL RULE 7.1(f)**

Pursuant to Local Rule 7.1(f), I hereby certify that this Memorandum of Law is 10 pages in length and complies with this Court's orders regarding procedures for filing pretrial motions (see Dkt. 1709, 1813) and is within the page limit allotted for this motion.

### /s/ Tara A. Fumerton

Tara A. Fumerton JONES DAY 77 West Wacker Chicago, IL 60601 Phone: (312) 269-4335

Fax: (312) 782-8585

E-mail: tfumerton@jonesday.com